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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/879,329	06/12/2001	Ethan R. Signer	408445	4053

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SALIWANCHIK LLOYD & SALIWANCHIK  
A PROFESSIONAL ASSOCIATION  
PO BOX 142950  
GAINESVILLE, FL 32614-2950

EXAMINER

SULLIVAN, DANIEL M

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 06/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/879,329

**Applicant(s)**

SIGNER ET AL.

**Examiner**

Daniel M. Sullivan

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4,6,10,12,14,15,17 and 18 is/are rejected.
- 7) ☒ Claim(s) 2,3,5,7-9,11,13,16,19 and 20 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION*****Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 15 April 2005 has been entered.

Claims 1-20 were considered in the Final Office Action mailed 15 October 2004. Claim 1 was amended in the 15 April Paper. Claims 1-20 are pending and under consideration.

***Response to Amendments*****Claim Rejections - 35 USC § 102 and 103**

Claims 1 and 4 **stand rejected** under 35 U.S.C. 102(e) as being anticipated by Bauer *et al.* U.S. Patent No. 6,534,315, claims 1, 6, 10, 12, 14 and 15 **stand rejected** under 35 U.S.C. 103(a) as being unpatentable over Bauer *et al.* and claims 1, 4, 17 and 18 **stand rejected** under 35 U.S.C. 103(a) as being unpatentable over Bauer *et al.* as applied to claims 1 and 4 above and further in view of Ow, D. (WO 93/01283).

In response to the *prima facie* case and arguments of record, Applicant has amended the claims to recite that the direct repeats are "effective for use in recombination with the genome of the host cells". In the Remarks, Applicant takes exception to the Office's previous assertion that the instant claims are not distinguished from the teachings of Bauer *et al.* by reciting that the direct repeats are "capable of recombination" because any DNA is capable of recombination.

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Applicant again points out that Bauer *et al.* teaches that the DRS thereof are not recombinogenic. Applicant urges that the amended claims now require that the direct repeats are effective for recombination with the genome of the host cells, and are directly opposite of what Bauer *et al.* teaches.

These arguments have been fully considered but are not deemed persuasive. Applicant is correct in pointing out that the dispute is one of semantics and Applicant is reminded that Office personnel are to give claims their broadest reasonable interpretation in light of the supporting disclosure. *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997). As stated in the previous Office Action, it is clear from the teachings of Bauer *et al.*, viewed as a whole, that non-recombinogenic does not mean incapable of recombination, which is inconsistent with the nature of DNA. It should be noted that Bauer *et al.* teaches that the DRS sequences can be “yeast DNA sequences not present in the host strain” (column 6, line 51). Thus, Bauer *et al.* teaches that the DRSs can be heterologous genes that are heterologous to the host cell genome, which is precisely what is comprised by the construct of the instant claims and provides the “random insertion mediated by the presently claimed DRSs” (2 August Paper, bridging pages 5-6).

The instant specification does not provide a limiting definition of “effective for use in recombination with the genome of the host cells”. Therefore, the Office must view this limitation as encompassing any sequence that could recombine with the genome of a host cell. While it is true that the direct repeats comprised within the constructs of Bauer *et al.* are constructed so as to minimize their contribution to recombination with the host cell genome, the repeats of Bauer *et al.*, like all DNA's, can recombine with the genome of host cells at some frequency. Therefore,

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the repeats would be effective, to some degree, for use in recombination with the genome of a host cell and the teachings of Bauer *et al.* anticipate the limitations of the instant claims for the reasons set forth in the previous Office Action and herein.

Applicant's arguments have been fully considered but are not deemed persuasive in view of the record as a whole. Therefore, the claims stand rejected under 35 USC §102 and 103 as anticipated by or obvious over the prior art.

#### ***Allowable Subject Matter***

Claims 2, 3, 5, 7-9, 11, 13, 16, 19 and 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Friday 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Daniel M. Sullivan, Ph.D.  
Examiner  
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